IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION
No. 5:07-CV-234-D

WYETH,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**ORDER**
	)	
SANDOZ, INC.,	)	
	)	
Defendant.	)	

Plaintiff Wyeth ("Wyeth") filed this patent-infringement action against Sandoz, Inc. ("Sandoz"), alleging that Sandoz's generic extended release venlafaxine product infringes U.S. Patent Nos. 6,274,171 B1 ("the '171 patent"), 6,403,120 Bl ("the '120 patent"), and 6,419,958 B2 ("the '958 patent") (collectively "the Wyeth patents"). Wyeth moved for summary judgment regarding Sandoz's direct infringement, active inducement of infringement, and contributory infringement of claims 20–25 of the '171 patent, claims 1, 2, 13, and 14 of the '120 patent, and claims 1–6 of the '958 patent [D.E. 118]. Sandoz, in turn, moved for summary judgment regarding Sandoz's noninfringement [D.E. 121] and concerning the alleged invalidity of the patents [D.E. 123]. The court granted Wyeth's motion for summary judgment and denied Sandoz's motions for summary judgment [D.E. 159].

Sandoz now moves for a certificate of appealability, seeking interlocutory review of two claim constructions underlying the summary judgment order: (1) whether the proper construction of the term "extended release formulation" is restricted to the specific ingredients set forth in the patents, and (2) whether infringement in this case is measured based on a patient-by-patient comparison or a patient-group-average comparison. As explained below, Sandoz's motion is denied.

I.

Wyeth manufactures Effexor® XR, an extended release venlafaxine hydrochloride medication that is used to treat depressive, social anxiety, and panic disorders. A division of Wyeth holds the FDA-approved New Drug Application ("NDA"), which encompasses the asserted claims. Sandoz seeks to market a generic extended release venlafaxine formulation and has filed an Abbreviated New Drug Application ("ANDA") with the FDA to effect this goal.

The patents-in-suit have not expired. Sandoz proves that the use of the ANDA product is safe and effective by claiming that the ANDA drug is bioequivalent to Effexor® XR, and by relying on Wyeth's studies to prove the safety and efficacy of the covered uses of Effexor® XR. See ANDA, Pl.'s Mem. Supp. Summ. J. Ex. 15 at S000356–82 (Summary of Biopharmaceutic Studies). Thus, the proven, approved uses — which Wyeth's asserted claims cover — are the only uses for which an ANDA applicant, such as Sandoz, may seek approval. Sandoz presents no new, unpatented uses for the FDA to consider.

Sandoz's ANDA provides undisputed facts about the proposed product. "The key difference between Effexor® XR and Sandoz's generic formulation is that Sandoz's formulation uses a different inactive ingredient (i.e., an Eudragit® polymer) to coat the encapsulated spheroids which contain the active pharmaceutical ingredient . . . ." Wyeth v. Sandoz, Inc. (Wyeth I), 570 F. Supp. 2d 815, 819 (E.D.N.C. 2008). Furthermore, the product, designed to "mimic[]" Effexor® XR's drug-release profile, ANDA, Pl.'s Mem. Supp. Summ. J. Ex. 15 at S000339, is a not a hydrogel tablet, and will provide therapeutic blood plasma concentration of the active ingredient venlafaxine hydrochloride over a twenty-four-hour period. See id. at S000327, S000357–82. Sandoz's proposed label for the ANDA product states that the product is formulated to be administered once a day. Draft Labeling, Pl.'s Mem. Supp. Summ. J. Ex. 17 at S000151. To provide a therapeutic level of drug concentration over a twenty-four-hour period, Sandoz's product contains "extended release pellets" that are the bioequivalent of Effexor® XR. ANDA, Pl.'s Mem. Supp. Summ. J. Ex. 15 at

S000327–29. Sandoz's proposed label for the ANDA product indicates that the product is for the treatment of patients with major depressive, social anxiety, and panic disorders. See Draft Labeling, Pl.'s Mem. Supp. Summ. J. Ex. 17 at S000156–58. Moreover, Sandoz describes the ANDA product as containing "spheroids." See id. at S000151.

The court held a Markman hearing to construe the disputed patent claims and familiarity with that order is presumed. Wyeth, 570 F. Supp. 2d at 833; see Markman v. Westview Instruments Inc., 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996). Wyeth thereafter moved for summary judgment regarding Sandoz's direct infringement, active inducement of infringement, and contributory infringement of claims 20–25 of the '171 patent, claims 1, 2, 13, and 14 of the '120 patent, and claims 1–6 of the '958 patent [D.E. 118]. Sandoz moved for summary judgment regarding Sandoz's noninfringement [D.E. 121] and concerning the alleged invalidity of the patents [D.E. 123]. The court granted Wyeth's motion for summary judgment and denied Sandoz's motions for summary judgment [D.E. 159]. See Wyeth v. Sandoz. Inc. (Wyeth II), No. 5:07-CV-234-D, 2010 WL 1404064, at *13 (E.D.N.C., March 12, 2010).

Sandoz now moves to certify two claim constructions underlying the summary judgment order for interlocutory review: (1) whether the proper construction of the term "extended release formulation" is restricted to the specific ingredients set forth in the patents, and (2) whether infringement in this case is measured based on a patient-by-patient comparison or a patient-group-average comparison.

II.

Under 28 U.S.C. § 1292(b), a district court may allow an interlocutory appeal of an otherwise nonappealable order when the movant establishes the following three things: (1) "[the] order involves a controlling question of law," (2) "there is substantial ground for difference of opinion" as to the controlling question of law, and (3) "an immediate appeal from the order may materially advance the ultimate termination of the litigation." 28 U.S.C. § 1292(b); see Yamaha Motor Corp.,

U.S.A. v. Calhoun, 516 U.S. 199, 204–05 (1996); Nystrom v. TREX Co., 339 F.3d 1347, 1351 (Fed. Cir. 2003); Sonoco Prods. Co. v. Physicians Health Plan, Inc., 338 F.3d 366, 370 n.5 (4th Cir. 2003). Interlocutory appeal under section 1292(b) is appropriate in "specific and limited circumstances." Sonoco Prods. Co., 338 F.3d at 370 n.5; James v. Jacobson, 6 F.3d 233, 237 (4th Cir. 1993) (recognizing the general rule that "piecemeal review of decisions that are but steps toward final judgments on the merits are to be avoided, because they can be effectively and more efficiently reviewed together in one appeal from the final judgments"); Fannin v. CSX Transp., Inc., No. 88-8120, 1989 WL 42583, at *2 (4th Cir. Apr. 26, 1989) (per curiam) (unpublished) (recognizing that interlocutory appeal is an "extraordinary remedy" and is appropriate in only "exceptional situations") (quotation omitted). Thus, the party seeking certification must persuade "the court . . . that exceptional circumstances justify a departure from the basic policy of postponing appellate review until after the entry of a final judgment." Fannin, 1989 WL 42583, at *2 (quotation omitted).

A question of controlling law is "a narrow question of pure law whose resolution will be completely dispositive of the litigation, either as a legal or practical matter, whichever way it goes." Id. at *5 (recognizing that although "a decision favorable to [the defendant] would certainly be one on a question of law that, as it had developed, was 'controlling,' this obviously cannot be all that is implied by the term"). Conversely, a question of law would not be controlling "if the litigation would necessarily continue regardless of how that question were decided." North Carolina ex rel. Howes v. W.R. Peele, Sr. Trust, 889 F. Supp. 849, 852–53 (E.D.N.C. 1995).

Sandoz requests that the court amend its summary judgment order of March 12, 2010, to certify two issues for interlocutory appeal: (1) whether the proper construction of the term "extended release formulation" is restricted to the specific ingredients set forth in the patents, and (2) whether infringement in this case is measured based on a patient-by-patient comparison or a patient-group-average comparison. See Def.'s Mem. Supp. 6–7. Sandoz argues that such claim-construction questions are ones of controlling law because they "resolve[] the infringement question with respect

to all of the patents-in-suit." Id. at 6. In support of its argument that the construction of "extended release formulation" is dispositive, Sandoz contends that under Sandoz's construction of the term, Sandoz would not infringe "because Sandoz's extended release venlafaxine formulation does not have the ingredients that are required" to infringe. Id. at 6–7.[1] In addition, Sandoz argues that the question of whether infringement is determined based on a patient-group-average versus on an individual patient-by-patient basis will resolve the issues of contributory infringement and inducement of infringement because "the universe of non-infringing uses [would be] substantially greater." Id. at 7.

Construction of a patent claim is a question of law for the court. See, e.g., Markman, 52 F.3d at 977 (collecting cases). In cases where an ANDA applicant may infringe claims encompassed by NDA, the infringement inquiry focuses on comparing "the use listed in the ANDA" with the use claimed in each patent limitation. See, e.g., Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1356 (Fed. Cir. 2003). Construction of a patent claim is often controlling, because the construction often resolves the question of direct infringement. See Mass. Inst. of Tech. & Elecs. for Imaging, Inc. v. Abacus Software, 462 F.3d 1344, 1350–51 (Fed. Cir. 2006); ATD Corp. v. Lydall, Inc., 159 F.3d 534, 539–40 (Fed. Cir. 1998).

An accused product infringes if it "incorporates every limitation of a claim, either literally or under the doctrine of equivalents." MicroStrategy Inc. v. Bus. Objects, S.A., 429 F.3d 1344, 1352 (Fed. Cir. 2005) (quotation omitted); see Wyeth II, 2010 WL 1404064, at *3. "A finding of infringement under the doctrine of equivalents requires a showing that the difference between the claimed invention and the accused product [i]s insubstantial." Crown Packaging Tech., Inc. v. Rexam Beverage Can Co., 559 F.3d 1308, 1312 (Fed. Cir. 2009). "One way of doing so is by showing on a limitation by limitation basis that the accused product performs substantially the same

[1]Sandoz argues that Wyeth acted as its own lexicographer and, therefore, construes "extended release formulation" as restricted to the specific ingredients set forth in the patents. See Wyeth, 570 F. Supp. 2d at 821.

function in substantially the same way with substantially the same result as each claim limitation of the patented product." Id.

In this case, the issues of claim construction on which Sandoz seeks interlocutory appeal are not dispositive because even if such issues were resolved in Sandoz's favor, the litigation would continue. Although Sandoz may not literally infringe if the Federal Circuit adopted its construction of "extended release formulation," Wyeth alternatively claims that Sandoz would infringe under the doctrine of equivalents. See, e.g., Am. Compl. ¶ 13. Consequently, even if the Federal Circuit were to adopt Sandoz's proposed claim construction, this court still would have to proceed to address the issue of infringement under the doctrine of equivalents.

As for Sandoz's argument that infringement should be measured based on a patient-by-patient comparison, rather than on a patient-group-average comparison, such an issue is not dispositive. Sandoz's label and its bioequivalency studies establish that numerous subjects, whether individually or as groups, have C_{max} and T_{max} values within the values covered by the Wyeth patents. See Draft Labeling, Pl.'s Mem. Supp. Summ. J. Ex. 17 at S000151–52; see also Pl.'s Mem Supp. Summ. J. 17–21. Essentially, in representing that the ANDA product is the bioequivalent of Effexor® XR, see Basis for ANDA, Pl.'s Mem. Supp. Summ. J. Ex. 20 at S000074; ANDA, Pl.'s Mem. Ex. 15 at S000332, S000336, Sandoz asserts that the ANDA product has effectively the same side effect profile, is equally effective, and is interchangeable with Effexor® XR. See Wyeth, 2010 WL 1404064, at *6; see also Abbott Labs. v. Sandoz, Inc., 566 F.3d 1282, 1298 (Fed. Cir. 2009) (en banc). Sandoz has not denied that this is the case. Thus, the ANDA product incorporates the covered limitations, regardless of whether such incorporation is measured based on a patient-by-patient comparison or on a patient-group-average comparison.[2]

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[2]Furthermore, for Sandoz's ANDA product to infringe, every patient who takes Sandoz's ANDA product need not achieve covered C_{max} and T_{max} values. See, e.g., Bell Commc'ns Research Inc. v. Vitalink Commc'ns Corp., 55 F.3d 615, 622–23 (Fed. Cir. 1995) (recognizing principle that "an accused product that sometimes, but not always, embodies a claimed method nonetheless

Sandoz responds that the specified issues of claim construction still are "controlling" because, in a different infringement action to which Wyeth was a party, Wyeth executed a settlement agreement after the district court construed the patent claims. See Def.'s Reply 2–3. However, this argument does not show whether the claim construction issues in this case are dispositive. See Fannin, 1989 WL 42583, at *5.

As for the second requirement under 28 U.S.C. §1292(b), the "substantial ground for a difference of opinion" must arise "out of a genuine doubt as to whether the district court applied the correct legal standard in its order." Consub Del. LLC v. Schahin Engenharia Limitada, 476 F. Supp. 2d 305, 309 (S.D.N.Y. 2007), aff'd, 543 F.3d 104 (2d Cir. 2008), abrogated in part on other grounds by Shipping Corp. of India Ltd. v. Jaldhi Overseas Pte Ltd., 585 F.3d 58 (2d Cir. 2009). "[T]he mere presence of a disputed issue that is a question of first impression [in the Federal Circuit], standing alone, is insufficient to demonstrate a substantial ground for difference of opinion." Flor v. Bot Fin. Corp (In re Flor), 79 F.3d 281, 284 (2d Cir. 1996) (per curiam). "Rather, it is the duty of the district judge to analyze the strength of the arguments in opposition to the challenged ruling when deciding whether the issue for appeal is truly one on which there is a substantial ground for dispute." Id. (quotation and alterations omitted); see Howes, 889 F. Supp. at 852. Moreover, "a court is not bound to find reasonable cause for disagreement whenever authorities lack unanimity." Howes, 889 F. Supp. at 852 (quotation and alteration omitted). "Indeed, a district court has the discretion to find a lack of substantial ground for difference of opinion even though the only other reported decision on the issue at hand disagrees with the conclusions of the court." Id.

Even if the claim construction issues in this case were dispositive, there is not substantial ground for a difference of opinion. Sandoz argues that there is substantial ground for difference of opinion as to the proper construction of "extended release formulation" and as to whether infringement should be measured based on a patient-group-average comparison. See Def.'s Mem.

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infringes").

Supp. 2–5, 8–9. In support, Sandoz contends that various prior infringement actions that Wyeth has filed have produced different definitions of "extended release formulation." Id. at 3. Additionally, in order to bolster its argument that substantial ground for difference of opinion exists as to whether infringement should be measured based on a patient-by-patient comparison, Sandoz focuses on the different definitions that exist as to the terms "diminished incidences of nausea and emesis," "about" with respect to C_{max}, and "in a patient." See id.

As for the construction of "extended release formulation," Sandoz notes that the district court in Wyeth v. Teva Pharms. USA, Inc., No. 03-CV-1293(WJM), 2005 WL 2175440 (D.N.J. Sept. 6, 2005) (unpublished), held that the term is limited to the ingredient-specific formulation set forth in the Wyeth patents. Id. at *7. The Teva court reasoned that "[a]lthough [such a construction] may make certain dependent claims coterminous and certain claim limitations superfluous, that result is inevitable and inescapable" because "the patentees act[ed] as their own lexicographers." Id.[3]

In contrast to Teva, this court adopted a broader construction of "extended release formulation": "A formulation, other than a hydrogel tablet, which releases the active ingredient at a slower rate than the immediate release formulation of the active ingredient such that the dosing frequency is once-a-day rather than the plural daily dosing for the immediate release formulation." Wyeth I, 570 F. Supp. 2d at 827–28. Moreover, other district courts have agreed with a broader construction of "extended release formulation." Compare id., with Wyeth v. Mylan Pharms., Inc., No. 1:07-CV-91, 2009 WL 1457732, at *4, *8, *22 (N.D.W. Va. May 22, 2009) (unpublished), and Wyeth v. Apotex Inc., No. 1:08-CV-22308-FAM, slip op. at 7–16 (S.D. Fla. Aug. 13, 2009) (unpublished) (magistrate judge report and recommendations), adopted by district court, No. 1:08-CV-22308-FAM (S.D. Fla. Oct. 8, 2009) (unpublished), and Wyeth v. Anchen Pharms., Inc., No. 06-386-JVS-AN, slip op. at 2–13 (C.D. Cal. Dec. 20, 2007) (unpublished in-chambers order),

[3]After the Teva court issued its Markman ruling, the parties settled and the Teva court vacated its Markman ruling. Teva Pharms. USA, Inc., No. 03-CV-1293(WJM) (D.N.J. Jan. 12, 2006) (unpublished).

and Wyeth v. Impax Labs., Inc., 526 F. Supp. 2d 474, 478–80 (D. Del. 2007); cf. also Wyeth v. Lupin Ltd., 579 F. Supp. 2d 711, 715–16 (D. Md. 2008) (unpublished) (adopting broader construction of "extended release formulation" but limiting the term to spheroids). As such, in light of the reasoning articulated in Wyeth, 570 F. Supp. 2d at 828, and after reviewing these various district court opinions, the court concludes that no substantial ground for difference of opinion exists as to whether "extended release formulation" is limited to specific ingredients. See Wyeth II, 2010 WL 1404064, at *6; Wyeth I, 570 F. Supp. 2d at 821–28; cf. Singh v. Daimler-Benz, AG, 800 F. Supp. 260, 263 (E.D. Pa.1992) (holding that, although sole other reported decision on the issue disagreed with the court's conclusions, no substantial ground for difference of opinion existed), aff'd, 9 F.3d 303 (3d Cir. 1993).[4]

In support of its argument that substantial ground for difference of opinion exists as to whether infringement should be measured based on a patient-group-average basis, Sandoz contends that different definitions exist as to the terms "diminished incidences of nausea and emesis," "about" with respect to C_{max}, and "in a patient." Def.'s Mem. Supp. 3. However, the differences in construction of these terms do not show substantial ground for difference of opinion as to whether infringement should be based on a patient-group comparison. In the Markman opinions, all but one of the courts that have addressed the issue agree that the appropriate comparison should be based on an average taken from a group of patients. Cf. Lupin Ltd., 579 F. Supp. 2d at 719 (determining that group comparison is appropriate); Wyeth I, 570 F. Supp. 2d at 829 (same); Anchen Pharms., Inc., No. 06-386-JVS-AN, at 14 (adopting Wyeth's proposed construction, which is based on "the mean value for the entire group of [study] subjects"). Conversely, the Apotex court construed "eliminating the troughs and peaks of blood concentration in a patient's blood plasma" to refer to individual

[4]Although the Teva and Lupin claim constructions were vacated, the court assumes (without deciding) that it may consider them in determining whether there is substantial ground for difference of opinion. Lupin Ltd., No. 07-CV-632(WDQ) (D. Md. Apr. 23, 2009) (unpublished); Teva Pharms. USA, Inc., No. 03-CV-1293(WJM) (D.N.J. Jan. 12, 2006) (unpublished).

patients rather than an average taken from multiple individuals because of the "plain reading" of the "in a patient[]." Apotex Inc., No. 1:08-CV-22308-FAM, slip op. at 20.

"That 'a' or 'an' can mean 'one or more' is best described as a rule, rather than merely as a presumption or even a convention." Baldwin Graphic Sys., Inc. v. Siebert, Inc., 512 F.3d 1338, 1342 (Fed. Cir. 2008). "The exceptions to this rule are extremely limited: a patentee must 'evince[ ] a clear intent' to limit 'a' or 'an' to 'one.'" Id. (quoting KCJ Corp. v. Kinetic Concepts, Inc., 223 F.3d 1351, 1356 (Fed. Cir. 2000)) (alteration in original). In light of this legal framework and the Abstract, Background, and Brief Description in the specifications of the Wyeth patents, see Wyeth I, 570 F. Supp. 2d at 829, the court does not believe the reasoning in Apotex provides a substantial ground for difference of opinion. Accordingly, Sandoz fails to show that the two issues of which it requests certification present issues of controlling law as to which there is substantial ground for difference of opinion.

Finally, as for whether an immediate appeal from the order may materially advance the ultimate termination of the litigation, the "mere fact" that "resolution at this time may save pre-trial and trial effort and expense is not determinative; that of course can be said of any interlocutory appeal." Fannin, 1989 WL 42583, at *5. For the same reasons that the issues are not questions of law that are controlling, immediate appeal will not materially advance the litigation in this case.

III.

Sandoz has failed to meet the standard necessary for an interlocutory appeal. See 28 U.S.C. § 1292(b). Accordingly, Sandoz's motion for a certificate of appealability [D.E. 160] is DENIED.

SO ORDERED. This 14 day of July 2010.

JAMES C. DEVER III
United States District Judge